(3) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(4) Approval of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device and data available to the agency do not establish that approval of the PMA, or the notice of completion of the PDP or amended or supplemental applications or notices, will result in release of substances that, at the expected levels of exposure, may be toxic to organisms in the environment.

(5) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(6) Promulgation of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(7) Action on an application for an Investigational Device Exemption (IDE) or an authorization to commence a clinical investigation under an approved Product Development Protocol (PDP), if the devices shipped under such notices are intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(8) Promulgation of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

[50 FR 16656, Apr. 26, 1985, as amended at 54 FR 9038, Mar. 3, 1989; 61 FR 14245, Apr. 1, 1996]

§ 25.25 Retroactive environmental consideration.

(a) FDA may consider the need for preparing an EIS for an existing FDA regulation, approval, or other action, whether or not previously subject to environmental analysis, when there is new information before the agency that suggests that the action may significantly affect the quality of the human environment.

(b) If FDA notifies an applicant or petitioner who obtained an existing FDA approval that new information suggests that the approval may have signficant environmental effects and that an EA is therefore required, the applicant or petitioner shall submit an EA as described in §25.31 for the approval. A notification under this paragraph will be in writing.

Subpart C—Preparation of Environmental Documents

§ 25.30 Content and format.

(a) Sections 25.31 through 25.34 describe the environmental documents that may be required in the course of the agency's consideration of the environmental aspects of an action. These sections delineate the relationships of these documents to each other and their purpose, contents, and format. Additional information concerning the nature and scope of information that an applicant or petitioner shall submit in an environmental document may be obtained on a case-by-case basis from the center, or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA environmental assessment technical guides, which describe protocols for environmental studies and discuss the interpretation of results.

(b) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in environmental documents prepared under this part. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner may submit such data and information separately as a confidential section of the application or petition, but shall summarize the confidential